FERROUS SULFATE- ferrous sulfate, dried tablet, film coated
SPIRIT PHARMACEUTICALS,LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

FERROUS SULFATE TABLETS USP 325 MG

Drug Facts

Active ingredients (in each Caplet)

Dried Ferrous Sulfate 325 mg

Purpose

Iron Supplement Therapy

Ferrous Sulphate is an iron supplement for iron deficiency and iron deficiency anemia when the need for such therapy has been determined by a physician.

Warnings

Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of a physician. Since oral iron products interfere with absorption of certain antibiotics, these products should not be taken within tow hours of each other. Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking with meals. Iron-containing products may occasionally cause constipation or diarrhea.

If are pregnant or nursing a baby, seek the advise of a health professional before using this products.

Warning: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Direction

* adults and children 12 years and over : take 1 tablet daily or as directed by a doctor
* Children under 12 years : consult a physician..

Other information

* Store at room temperature

Inactive ingredients

Starch USP, Calcium Carbonate USP, Guar Gum , Magnesium Stearate USP, Talc USP, Colloidal Silicon Dioxide USP, , Carnuba Wax

PRINCIPAL DISPLAY PANEL - Shipping Label

FERROUS SULFATE TABLETS USP 325 MG

Each film coated tablet contains:
Ferrous Sulfate tablet USP 325 mg
(Equivalent to 65 mg of elimental IRON)

LOT NO	:	QUANTITY	: 15000
DRUM NO	:	NDC NO	: 68210-1520-1
MFG. DATE	:	EXP. DATE	:

WARNING :
KEEP OUT OF THE REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPRATURE OF 59° – 86°F (15° – 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT
CONFORMANCE WITH THE F.D & C.ACT AND REGULATIONS THEREUNDER

MANUFACTURED BY:
LIC NO : GUJ/DRUGS/G/505
MARKSANS PHARMA LTD
UDYOGNAGAR,NAVSARI-396445
INDIA

MANUFACTURED FOR:
SPIRIT PHARMACEUTICALS LLC
225 LINCOLN HWY, STE 205
FAIRLESS HILLS , PA 19030
PH.# 215 943 4000, FAX.#215 943 4039

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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FERROUS SULFATE

ferrous sulfate, dried tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-1520
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS SULFATE, DRIED (UNII: RIB00980VW) (IRON - UNII:E1UOL152H7)	FERROUS SULFATE, DRIED	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
GUAR GUM (UNII: E89I1637KE)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	TRIANGLE	**Size**	14mm
Flavor		**Imprint Code**	FS
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68210-1520-1	1 in 1 DRUM		
1		15000 in 1 BAG		
2	NDC:68210-1520-2	1 in 1 DRUM		
2		10000 in 1 BAG		
3	NDC:68210-1520-3	1 in 1 DRUM		
3		1000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

UNAPPROVED DRUG OTHER		12/15/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 12/2010 SPIRIT PHARMACEUTICALS,LLC